



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

SHIFF *et al.*

Application No. 09/006,999

Filed: January 14, 1998

For: APPARATUS FOR THE
SEPARATION OF CYSTIC
PARASITE FORMS FROM
WATER

RECEIVED

FEB 23 2004

Art Unit: 2856

Examiner: M. Cygan

Atty. Docket No. 2240-171353

Customer No.

26694

PATENT TRADEMARK OFFICE

APPEAL BRIEF

Board of Patent Appeals and Interferences
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Appellants submit herewith their Appeal Brief in triplicate, pursuant to 37 C.F.R.
§1.192.

REAL PARTIES IN INTEREST

The real parties in interest are Johns Hopkins University, by virtue of assignment from the Appellants, and Clean Water Technologies, Inc., by virtue of a license agreement with Johns Hopkins University.

RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to the Appellants or the Appellants' legal representative, or the assignee, that will directly affect or will be directly affected by or have bearing on the Board's decision in this appeal.

02/19/2004 SZEWDIE1 00000108 09006999

01 FC:2402

165.00 0P

STATUS OF CLAIMS:

Claims 1, 4, 6-8 and 10-12 have been finally rejected by the Examiner and are at issue in this appeal. The claims on appeal are set forth in the Appendix to this brief.

STATUS OF AMENDMENTS

One response, dated July 8, 2003, has been submitted subsequent to the Examiner's final rejection of March 17, 2003. The response contained no claim amendments. The Examiner's Advisory Action of July 23, 2003 indicated that the response had been considered.

SUMMARY OF THE INVENTION

The invention is a continuous flow centrifuge apparatus, with an improvement comprising the addition of a filtration column of particulate material, and a method for concentrating or isolating a microorganism from an aqueous suspension using the apparatus (described in the specification at page 5, line 9 to page 6, line 14). Filtration within a tube of water under the forces of centrifugation is used to separate small parasite products (of 4-10 microns in diameter) from raw water. The improved apparatus can perform filtration of 20 liters or more of water already containing particulates and colloidal matter per sample, and is efficient in removing *Cryptosporidium* oocytes for purification or testing.

ISSUES:

1. Whether the Examiner's rejection of claim 1 under 35 USC § 102(b) as being anticipated by Mudambi et al. (Proceed. 26th Conf Great Lakes Res., May 1983) should be reversed.

2. Whether the Examiner's rejection of claims 1, 4, 6-8 and 10-12 under 35 USC § 103(a) as being unpatentable over Whitmore and Carrington (Wat. Sci. Tech. 1993) in view of Olsson (U.S. Pat. No. 5,019,497) should be reversed.

3. Whether the Examiner's rejection of claims 1, 4, 6-8 and 10-12 under 35 USC § 103(a), as being unpatentable over Borchardt et al. (U.S. Pat. No. 5,846,439) in view of Leu (U.S. Pat. No. 5,866, 071), should be reversed.

GROUPING OF THE CLAIMS:

The claims should be considered separately for the purposes of patentability for the reasons set forth below.

THE EXAMINER'S POSITION:

1. It is the Examiner's position that claim 1 is anticipated by Mudambi et al. (Proceed. 26th Conf. Great Lakes Res., May 1983).

2. It is the Examiner's position that the combination of Whitmore and Carrington with Olsson results in the invention as claimed in claims 1, 4, 6-8 and 10-12¹ and that the claims are therefore obvious in view of the cited art.

3. It is the Examiner's position that the combination of Borchardt et al. with Leu results in the invention as claimed in claims 1, 4, 6-8 and 10-12 and that the claims are therefore obvious in view of the cited art.

ARGUMENT:

1. Rejection over Mudambi et al.

It is the Examiner's position that Claim 1 is anticipated by Mudambi et al. Appellants respectfully disagree.

The device used by Mudambi et al. is a milk separating machine made by Alfa-Laval. After passage through the separator, the particle-free water was then passed through a column containing the XAD-8 adsorbent. The process of *adsorption* is different from filtration, as is carried out in the present invention. In the process of Mudambi et al., the molecules of the contaminant are adsorbed to the surface of the matrix (XAD-8) and removed from the water. Subsequently, these molecules are eluted

¹ The Examiner referred to claims 1, 4, 6-8 and 10-13 in this rejection. However, there has never been a claim 13 pending in the case.

from the matrix and passed through a complex analytical apparatus. Furthermore, the filtration step is separate from the centrifugation step in the device and process of Mudambi *et al.* The device of the present invention combines the filtration column in the centrifuge, so that concentration and filtration occurs simultaneously and the particles trapped in the filter can be eluted and examined microscopically after the main filtration process. This allows for great economy of time and material.

The device of Mudambi *et al.* was developed to remove extraneous particles from water sample prior to the determination of the organic contaminant Mirex, which was present in picogram quantities. The procedure and principle are completely different from the concept of the present invention, which includes a filtration process within the centrifuge and is concerned with larger particulate matter.

For these reasons, Appellants respectfully submit that the apparatus of Claim 1 is not anticipated by Mudambi *et al.* Accordingly, it is respectfully requested that the 35 USC § 102(b) rejection of claim 1 be reversed

2. Rejection over Whitmore *et al.* in view of Olsson

It is the Examiner's position that claims 1, 4, 6-8 and 10-12 are obvious over Whitmore *et al.* (Wat. Sci. Tech. 1993) combination with U.S. Pat. No. 5,019,497 (Olsson). Appellants respectfully disagree.

According to the Examiner, the Whitmore *et al.* reference discloses the claimed invention, a continuous flow centrifuge and method of using the centrifuge to recover cryptosporidium from water, except for the use of a particulate column in the centrifuge apparatus. The Examiner further states that Olsson teaches the use of a particulate column mounted in a centrifuge tube to catch the flow through containing a desired sample material. The Examiner concludes that it would be obvious to use a particulate column as taught by Olsson in the invention taught by Whitmore *et al.* to filter the desired material from water.

Whitmore *et al.* compare a variety of methods for the removal and identification of *Cryptosporidium* oocysts. They clearly state in the abstract that the Membrex standard method of removing *Cryptosporidium* oocysts consisted of passing large volumes of

water through cartridge filters, but this was tedious and recoveries were only of the order of 30-40%. They tried a continuous centrifuge with very low recovery because they did NOT incorporate the filter within the centrifuge itself, hence very poor recovery was made compared with the present invention. There is no teaching or suggestion in Whitmore et al. to incorporate the filter within the centrifuge, as was done in the present invention.

Olsson uses a small Sephadex column mounted in a centrifuge tube to catch the flow through containing labeled proteins, which are of a completely different size range and form than the microorganisms to be isolated by Whitmore et al., and by the present invention. There is no suggestion in either Olsson or Whitmore et al. that would have led a person of skill in the art to combine the two disclosures, as one concerns labeled proteins, and the other concerns microorganisms. Furthermore, even if the disclosures were combined, it would not have resulted in the present invention. Olsson does not mention sand or glass beads, nor anything of that form, as a filtration particle, and Whitmore et al. teaches away from the use of sand, as exemplified by the statement in the abstract "the system was judged inadequate for monitoring because of the poor retention of oocysts within the column matrix at realistic flow rates." The statement cited by the Examiner:

"continuous flow centrifuges tested were not shown to be capable of yielding satisfactory recoveries, although it is considered more refined machines currently available may warrant investigation" (page 3 second paragraph of the Office Action issued March 17, 2003)

is at best an "invitation to experiment", and would not lead a skilled artisan to combine Whitmore et al. with Olsson. This statement would be better characterized as teaching away from the use of continuous flow centrifuges, as taught and claimed by Appellants.

Whitmore et al. did NOT incorporate the filter within the centrifuge itself, as does the present invention, and achieved a very poor recovery compared with the present invention. It is respectfully submitted that the combination of Whitmore et al. with Olsson would not have lead a skilled artisan to incorporate a filter within a continuous flow centrifuge, as in the present invention, and thereby achieve the superior results of the present invention.

For these reasons, it is respectfully submitted that the combination of Whitmore *et al.* and Olsson does not render the present invention obvious. Accordingly, it is respectfully requested that the 35 USC § 103 rejection of claims 1, 4, 6-8 and 10-12 be reversed.

3. Rejection over Borchardt *et al.* in view of Leu

It is the Examiner's position that the combination of Borchardt *et al.* with Leu results in the invention as claimed in claims 1, 4, 6-8 and 10-12 and that the claims are therefore obvious in view of the cited art. It is noted that this rejection was vacated by the Board in the Decision dated September 27, 2002 and that the present claims are the same as those on appeal in that Decision.

The Examiner stated that with respect to claim 1, Borchardt *et al.* teaches the claimed invention except for the use of a particulate filtrate column. Appellants respectfully disagree. The Borchardt patent teaches the use of a continuous separation channel centrifuge, as depicted in Figure 1 of U.S. Pat. No. 5,846,439. The centrifuge used in the methods according to the present invention is completely different, as shown in Figure 1 of the present application. In the method taught by Borchardt *et al.*, collected parasites are retained in the channel labeled "12" in Figure 1. In Appellants' invention, parasites are collected in replaceable sample tubes. It is respectfully submitted that a filtration column of particulate material, as employed in the present invention, cannot be added to a channel as taught by Borchardt *et al.* Furthermore, in the method disclosed by Borchardt *et al.*, the collected material must be removed from the separation channel before a subsequent sample can be processed.. In Appellants' claimed method, the sample collection tubes need merely be replaced.

Appellants also respectfully submit that the centrifuge apparatus used by Borchardt *et al.* is far more complex than that of the present invention, and would not be operable for the purposes of the present invention. Any apparatus used for these purposes must perform with natural water with various quantities of sediment. A delicate piece of apparatus designed for medical work, as used by Borchardt *et al.*, that was designed to centrifuge a few liters of blood, cannot handle quantities up to 20-30 liters of

water. In particular, it is noted that the Borchardt patent indicates in column 9, lines 24-25, that filtration of 100 liters of pond water required 11 hours in their apparatus. In the presently claimed apparatus and method, 20 or 25 liters of pond water can be filtered in 25-27 minutes.

Finally, it is respectfully submitted that the Borchardt patent "teaches away" from the present invention. For example, at column 2, lines 28-29, it is stated that "the sand column system was judged inadequate for monitoring because of the poor retention of oocytes..."

The Leu patent does not remedy the deficiency of the Borchardt patent to suggest the present invention. First, there is no suggestion in either Borchardt *et al.* or Leu that would motivate a person skilled in the art to combine the two documents. The Borchardt patent is directed to the use of a continuous separation channel centrifuge, whereas the Leu patent is directed to a centrifuge tube to be used for separation after density gradient centrifugation. These two processes are inherently different. Furthermore, there does not appear to be any way that the centrifuge tube of Leu can be combined with Borchardt *et al.* to yield the present invention. In addition, the centrifuge tube of Leu is designed for removal of gradients following centrifugation, and not for operation during the centrifugation process itself. It is respectfully submitted that even were the teachings of these two patents able to be combined, it would not result in the present invention. Finally, as noted above, Borchardt *et al.* teaches away from the use of a sand column system, and makes no mention of glass beads. Thus, the suggestion to use the required element of a filtration column of particulate material is missing from the teachings of these documents. For all of these reasons, it is respectfully submitted that the invention claimed in claim 1 is not obvious in view of Borchardt *et al.* combined with Leu. Accordingly, reversal of the Examiner's 35 USC § 103 rejection of claim 1 is respectfully requested.

With respect to claims 4 and 12, it is the Examiner's position that Borchardt *et al.* in view of Leu teaches the claimed invention as stated above except for the use of glass or sand particulate material, and that Borchardt *et al.* discloses that it is known in the art to use sand columns to filter oocytes from water in flow systems. According to the

Examiner's position, it would be obvious to use sand columns in the centrifuge of Borchardt et al. in replacement of the media of Leu. Appellants respectfully disagree. Although Borchardt et al. mentions the use of sand, generally, it is in the context of discussing the failure of sand filtration to adequately separate oocysts from water. There is no teaching or suggestion in the Borchardt patent that sand columns, or filtration columns of any kind, be used in a continuous flow centrifuge, as in the present invention. For these reasons, reversal of the 35 USC § 103 rejection of claims 4 and 12 over Borchardt et al. in combination with Leu is respectfully requested.

With respect to claims 6-8, it is the Examiner's position that Borchardt et al. teaches that it is known in the art to perform microorganism, cryptosporidium in particular, concentration in a fluid stream of a continuous flow centrifuge (col. 2, lines 41-42). Appellants respectfully submit that regardless of whether this statement is true, that neither Borchardt et al. nor any other reference relied on by the Examiner teaches the incorporation of a filtration column of particulate material, as recited in claim 1 and therefore required by dependent claims 6-8. For these reasons, reversal of the 35 USC § 103 rejection of claims 6-8 over Borchardt et al. in combination with Leu is respectfully requested.

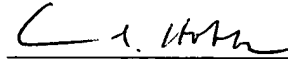
With respect to claims 10-11, it is the Examiner's position that the selection of size ranges of sand or glass beads is a matter of routine experimentation. Appellants respectfully submit that the basic apparatus and method of the present invention recited in these claims, the addition of a filtration column of particulate material to a continuous flow centrifuge, is not taught or suggested, and that accordingly, there is no device or method for which selection of particle sizes and column height is possible. For these reasons, reversal of the 35 USC § 103 rejection of claims 10-11 over Borchardt et al. in combination with Leu is respectfully requested.

CONCLUSION

In summary, Appellants submit that claims 1, 4, 6-8 and 10-12 are clearly novel and unobvious over the prior art. It is respectfully requested that the Examiner's rejections under 35 USC §§102 and 103 be reversed and the application be passed to issue.

Respectfully submitted,

Dated: 2/18/04



Ann S. Hobbs

Registration No. 36,830

VENABLE

Post Office Box 34385

Washington, D.C. 20043-9998

Telephone: (202) 962-4800

Telefax : (202) 962-8300

APPENDIX

Claims on appeal:

1. In a continuous flow centrifuge apparatus, the improvement comprising the addition of a filtration column of particulate material.
2. (canceled)
3. (canceled)
4. The apparatus of claim 1 in which said particulate material is graded glass beads or sand.
5. (canceled)
6. A method for concentrating or isolating a microorganism from an aqueous suspension, said method comprising centrifuging said solution using the apparatus of claim 1.
7. In a method for concentrating, isolating or detecting a microorganism using a continuous flow centrifuge, the improvement comprising using a filtration column of particulate material in the fluid stream of the centrifuge.
8. The method of claim 7 in which the microorganism is a cyst of cryptosporidium or giardia.
9. (canceled)
10. In a continuous flow centrifuge apparatus, the improvement comprising the addition of a filtration column of particulate material, wherein said particulate material is selected from the group consisting of graded glass beads of 120-50 μm and fine sand of 200-50 μm and the column is at least about 7 cm in height.
11. A continuous flow centrifuge apparatus which is adapted to include a filtration column of particulate material having a size range of 120-50 μm .
12. In a method for concentrating, isolating or detecting a cyst of cryptosporidium or giardia using a continuous flow centrifuge, the improvement comprising using a filtration column of graded glass beads or sand in the fluid stream of the centrifuge.